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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/770,342

Applicant(s)

FLEISCHHACKER, MARK G.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed September 11, 2003. The Examiner acknowledges the Declaration under 37 C.F.R. § 1.131. The Examiner further acknowledges that no amendments were made to the specification, claims or drawings in the response. Claims 1-21 are pending.

#### ***Claim Objections***

2. Claim 11 is objected to because of the following informalities: in line 2, "polymerical" apparently should read --polymeric--. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12, 16, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne ('640). Osborne teaches a composite guide wire shaft. Osborne teaches several embodiments for the composite guide wire shaft. With the exception of the "hybrid" embodiment disclosed at column 5, lines 35-54, the guide wires include a core wire that has proximal, medial and distal segments where the core wire is formed of a non-metallic, non-woven material. The core wire may be formed of a plurality of fibers chosen from a group

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consisting of boron fibers, carbon fibers, fiberglass, polymeric aromatic nylon fibers, silicon carbide filaments, or the like (column 4, lines 7-11). The fibers are bonded to one another by being embedded in an adhesive matrix such that the tiny spaces between the wires are substantially filled with the adhesive (column 2, lines 44-47). The adhesive matrices can be formed of a variety of binder resins, such as epoxy resins, polyester resins, vinyl ester resin-type glues, and cyanoacrylates (column 4, lines 15-24). The core wire may be formed entirely of polymeric materials. The core wire may also be provided with an outer sleeve formed of polyethylene, Teflon ®, nylon or other suitable shrinkable material that may be provided with a hydrophilic outer coating (column 5, lines 7-20). The core wire may have proximal, medial and distal segments that have the same diameters (Figure 1) or distally tapered segments (Figure 2) that have increasing flexibility. As disclosed at column 5, lines 21-34, the core wire may include multiple, short non-metallic fibers that are "mixed" into the binder matrix. The term "mixed" implies that the fibers are randomly-disposed within the matrix and that the binder resin fills any void space between the fibers. The core wire may be provided with a helical coil on an outer surface of its distal end (column 5, lines 51-52).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Sirhan et al. ('875). Osborne, as discussed hereinabove, teaches all of the limitations of the claims except that the core wire comprises polyetheretherketone. Sirhan et al. teach that polyetheretherketone is known to be a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use polyetheretherketone to make a core wire similar to that of Osborne in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters to form the fibers.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Nobuhiko ('263). Osborne, as discussed hereinabove, teaches all of the limitations of the claim except that the core wire is coated with PEBAX polyetherimide. Nobuhiko teaches coating a guidewire core 1 with PEBAX polyetherimide 2 to provide the guidewire with prolonged lubricating ability. It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use PEBAX polyetherimide to coat a core wire similar to that of Osborne in view of the teachings of Nobuhiko in order to provide the guidewire with prolonged lubricating ability.

8. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne ('640) in view of Sirhan et al. ('875), and further in view of Moutafis et al. ('620).

Osborne, as discussed hereinabove, teaches a guidewire having a core wire formed of

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polymeric materials that is substantially completely covered with a second polymeric material.

Osborne teaches all of the limitations of the claims except that polyetheretherketone and polyetherimide are used as the polymeric materials for construction.

Sirhan et al. teach that polyetheretherketone is known as a conventional polymeric material that is suitable for constructing guidewires and catheters (col. 9, lines 46-53). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use a polyetheretherketone to make a core wire similar to that of Osborne in view of the teachings of Sirhan et al. as a design choice, merely selecting a conventional polymeric material that is known to be suitable for the construction guidewires and catheters.

Osborne, as modified by Sirhan et al., teach all of the limitations of the claims except that the core wire is coated with polyetherimide. Moutafis et al. teach a plastic coated medical guidewire where a core wire is coated by a polyetherimide sleeve **14** (col. 3, lines 61-65) which is further coated with a hydrophilic lubricous coating **20** (col. 4, line 33). It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to coat a polyetheretherketone a core wire similar to that of Osborne as modified by Sirhan et al., with a polyetherimide jacket and a lubricous coating in view of the teachings of Moutafis et al. as a design choice, merely selecting conventional polymeric materials to construct a guidewire that are known to provide a guidewire with steerability, flexibility, resistance to kinking and stiffness, and lubricity.

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***Response to Arguments***

9. Applicant's arguments filed September 11, 2003, with respect to the rejections of claims 1-21 under 35 U.S.C. 102(e) and 103(a) have been fully considered and are persuasive. The Declaration under 37 C.F.R. 1.131 filed September 11, 2003 eliminates the Cordis Corporation reference and the Solar et al. reference as valid prior art in the instant application. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Osborne which was issued more than six years prior to the earliest priority date of the instant application.

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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November 20, 2003